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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/283,431 04/01/99 ZHOU

W 475.08.423

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HM12/0928

EXAMINER

LACOURCIERE, K

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 09/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 09/283,431	Applicant(s) ZHOU ET AL.	
	Examiner Karen A. Lacourciere	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 July 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or

**WILLIAM N. PHILLIPS**  
**PATENT ANALYST**

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4-6 are maintained as rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record set forth in the Office action mailed 04-20-01.

Claims 4-6 are indefinite due to the recitation "one or more POPS blocks". "POPS blocks" have been defined as regions of alternating phosphodiester and phosphorothioate internucleoside linkages. As defined, a single "POPS block" does not have a specified length and, as such, one skilled in the art would not be able to differentiate between a single "POPS block" and a series of "one or more" contiguous "POPS blocks".

Claims 4-6 are as indefinite due to the recitation "flanked". As written, one skilled in the art would not be able to determine if each individual "POPS block" is flanked by one or more regions of 2'-O-modified regions or if the "POPS blocks" are contiguous, resulting in a core region of "POPS" flanked by one or more 2'-O-modified regions.

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*Response to Arguments*

3. Applicant's arguments filed July 23, 2001 have been fully considered but they are not persuasive.

In response to the rejection of claims 4-6 under 35 U.S.C. 112, second paragraph, set forth in the Office action mailed 04-20-01, Applicant argues that claim 4 has been amended to limit all of the internucleoside linkages to phosphodiester, phosphotriester, phosphorothioate or phosphoramidate. The amendment to claim 4 reciting "the internucleoside linkages" lacks antecedent basis and is indefinite as to which linkages are limited to phosphodiester, phosphotriester, phosphorothioate or phosphoramidate. Further, it is unclear how the "POPS block" region can comprise phosphotriester or phosphoramidate linkages, therefore, the rejection under 35 U.S.C. 112, second paragraph has been maintained.

In response to the rejection of claims 4-6 under 35 U.S.C. 112, second paragraph, set forth in the Office action mailed 04-20-01, Applicant argues that one skilled in the art would understand that one POPS block is a region of 3 to 35 nucleosides of alternating phosphodiester and phosphorothioate linkages flanked by a region of 2'-O-substituted ribonucleotides constitutes a single POPS block and not a series of contiguous POPS blocks. This is not found to be persuasive because "POPS blocks" is not a term of art and the definition of "POPS blocks" provided in the specification does not indicate that the boundary of a single "POPS block" is defined by a flanking 2'-O-ribonucleotide region. The description provided by the specification seems to indicate multiple POPS blocks occur within a region of alternating phosphorothioate and

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phosphodiester linkages since at least one POPS block within such a region is required to maintain a ratio of between 1:3 and 3:1 PO:PS (see for example page 3, paragraph 2). Therefore, the rejection of record has been maintained.

*New Grounds of Rejection*

*Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the internucleoside linkages" in the sixth line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claims 5 and 6 are indefinite for the same reasons due to their dependence on claim 4.

Claim 4 is further indefinite because if all of the internucleoside linkages in the claimed oligonucleotide are selected from the group consisting of phosphodiester, phosphotriester, phosphorothioate and phosphoramidate, it is unclear if the "POPS block" region can include phosphodiester, phosphotriester, phosphorothioate and phosphoramidate linkages or if the "POPS blocks" region contains only phosphodiester and phosphorothioate bonds.

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Claim 4 is indefinite due to the recitation "POPS blocks". The term "POPS blocks" is not a term of art and has not been defined in the specification such that one skilled in the art could determine the metes and bounds of the term "POPS blocks". The specification provides a description of "POPS blocks" on page 3 (paragraph 2) and on page 6 (paragraphs 3 and 4), which describes various preferred embodiments of "POPS blocks", however, the description provided does not define the metes and bounds of the term "POPS blocks" clearly. For example, the description states that the region of alternating PO and PS bonds may be irregular, so long as a ratio of 1:3 to 3:1 is maintained in "at least one" POPS block, however, one skilled in the art would not determine where one POPS block ends and another begins within a region comprising multiple contiguous POPS blocks, particularly since the length of a "POPS block" can vary from about 3 to about 35 nucleobases long. Claims 5 and 6 are indefinite for the same reasons due to their dependence on claim 4.

### *Conclusion*

Any rejection of record not repeated herein is considered to be withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523.

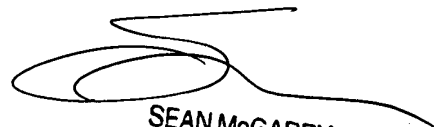
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at (703) 308-0447. The fax phone number for this Group is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere

September 26, 2001



SEAN MCGARRY  
PRIMARY EXAMINER